Notice of Allowability	Application No.	Applicant(s)	
	10/057,532	LYON ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *3/14/07*.

2. ☒ The allowed claim(s) is/are *1, 3, 5, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 and have been renumbered as 1-13*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *5/17/07*.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

1. Applicant's amendment filed on 3/14/07 is acknowledged.

Status of Claims

2. Claims 1, 3, 5, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 are currently pending.

Examiner's amendment

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ann S. Hobbs, Ph.D on 5/24/07 (see attached interview summary). The application has been amended as follows:

1. (currently amended) A vaccine comprising a C-terminal 42 kD fragment of merozoite surface protein-1 ($MSP1_{42}$) from *P. falciparum* 3D7 ~~as~~ set forth ~~in~~ as SEQ ID NO:7, that is recombinantly expressed in *E. coli* as a soluble protein that retains its native structure, and an adjuvant.

3. (currently amended) A method for inducing an immune response to malaria in a subject comprising administering to said subject a composition comprising an immunologically effective amount of C-terminal 42 kD fragment of merozoite surface protein- 1 ($MSP1_{42}$) from *P. falciparum* 3D7 ~~as~~ set forth ~~in~~ as SEQ ID NO:7, that is recombinantly expressed in *E. coli* as a soluble protein that retains its native structure in an acceptable diluent and an adjuvant.

5. (currently amended) A method for inducing a protective immune response to malaria in a mammal, comprising administering a composition comprising a $MSP1_{42}$from *P. falciparum* 3D7 ~~as~~ set forth ~~in~~ as SEQ ID NO:7, that is recombinantly expressed in *E. coli* as a soluble protein that retains its native structure in an amount effective to induce an immune response in said mammal and an adjuvant.

12 . currently amended) The vaccine of claim 1, wherein the adjuvant is a formulation of 0.25 mg cholesterol, 1 mg dioleoyl phosphotidylcholine, 50 µg 3D-MPL, and 50 µg QS21, said formulation consisting of small liposomes, wherein the QS21 and the 3D-MPL are in the membranes of the liposomes.

13. currently amended) The vaccine of claim 1, wherein the adjuvant is a formulation of 10.68 mg squalene, 11.86 mg tocopherol, 4.85 mg Tween 80, 50 µg 3D-MPL, and 50 µg QS21 and said formulation

consisting of an oil-in-water emulsion comprising the squalene and alpha-tocopherol, ~~the emulsion being~~ in admixture with the QS21 and 3D- MPL.

14. currently amended) The vaccine of claim 1, wherein the adjuvant is a formulation of 0.25 mg cholesterol, 1 mg dioleoyl phosphotidylcholine, 50 µg 3D-MPL, 50 µg QS21 and 0.5 mg AlOH3, said formulation consisting of small liposomes wherein the QS21 and 3D-MPL are in the membranes of the liposomes and wherein the liposomes and ~~the antigen~~ ~~said~~ the protein, SEQ ID NO:7, are absorbed onto a metallic salt particle carrier.

15. currently amended) The vaccine of claim 1, wherein the adjuvant is a formulation of 0.5 mg AlOH3, and 500 mg of unmethylated immunostimulatory oligonucleotide CpG, wherein ~~antigen~~ ~~said~~ the protein, SEQ ID NO:7, and ~~immunostimulant~~ unmethylated immunostimulatory oligonucleotide (CpG) are absorbed onto a metallic salt particle carrier.

16. currently amended) The vaccine of claim 1, wherein the adjuvant is a formulation of 0.25 mg cholesterol, 1 mg dioleoyl phosphotidylcholine, 50µg QS21, and 0.5 mg AlOH3, said formulation consisting of small unilamellar vesicles wherein the QS21 is in the membranes of the vesicles and wherein the vesicles and ~~the antigen~~ ~~said~~ the protein, SEQ ID NO:7, are absorbed onto a metallic salt particle carrier.

4. In view of amendment to the claims all the rejections of record are withdrawn.

5. Merozoite surface protein-1 ($MSP1_{42}$) from *P. falciparum* 3D7, set forth as SEQ.ID.NO: 7 is construed as consisting of SEQ.ID.NO: 7 , obtained from Escherichia coli BL 21 (DE3) containing the plasmid pET42AT(NK2) ,PTA-5976. The protein having made in Escherichia coli BL 21 (DE3) has high solubility and hence is a vaccine grade protein. The prior art does not teach or suggest the vaccine or a method of inducing protective immune response comprising a C-terminal 42 kD fragment of merozoite surface protein-1 ($MSP1_{42}$) from *P. falciparum* 3D7 set forth as SEQ ID NO:7.

6. Claims 1, 3, 5, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 are allowed and have been renumbered as 1-13 respectively.

7. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600

Padma Baskar Ph.D.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

CLEAN COPY OF CLAIMS

1. A vaccine comprising a C-terminal 42 kD fragment of merozoite surface protein-1 ($MSP1_{42}$) from *P. falciparum* 3D7 set forth as SEQ ID NO:7, that is recombinantly expressed in *E. coli* as a soluble protein that retains its native structure, and an adjuvant.

3. A method for inducing an immune response to malaria in a subject comprising administering to said subject a composition comprising an immunologically effective amount of C-terminal 42 kD fragment of merozoite surface protein- 1 ($MSP1_{42}$) from *P. falciparum* 3D7 set forth as SEQ ID NO:7, that is recombinantly expressed in *E. coli* as a soluble protein that retains its native structure in an acceptable diluent and an adjuvant.

5. A method for inducing a protective immune response to malaria in a mammal, comprising administering a composition comprising a $MSP1_{42}$from *P. falciparum* 3D7 set forth as SEQ ID NO:7, that is recombinantly expressed in *E. coli* as a soluble protein that retains its native structure in an amount effective to induce an immune response in said mammal and an adjuvant.

7. The method of claim 5, wherein the composition is administered to the individual in an amount of 50 ug per dose.

8. The method of claim 5, wherein the composition is administered parenterally.

9. The method of claim 5, wherein the composition is administered intranasally.

10. The method of claim 5, wherein said administration is a multiple administration.

11. The method according to claim 10 wherein said multiple administration is at 0 and 6 months.

12 . The vaccine of claim 1, wherein the adjuvant is a formulation of 0.25 mg cholesterol, 1 mg dioleoyl phosphotidylcholine, 50 µg 3D-MPL, and 50 µg QS21, said formulation consisting of small liposomes, wherein the QS21 and the 3D-MPL are in the membranes of the liposomes.

13. The vaccine of claim 1, wherein the adjuvant is a formulation of 10.68 mg squalene, 11.86 mg tocopherol, 4.85 mg Tween 80, 50 µg 3D-MPL, and 50 µg QS21 and said formulation consisting of an oil-in-water emulsion comprising the squalene and alpha-tocopherol, in admixture with the QS21 and 3D-MPL.

14. The vaccine of claim 1, wherein the adjuvant is a formulation of 0.25 mg cholesterol, 1 mg dioleoyl phosphotidylcholine, 50 µg 3D-MPL, 50 µg QS21 and 0.5 mg AlOH3, said formulation consisting of small liposomes ,wherein the QS21 and 3D-MPL are in the membranes of the liposomes and wherein the liposomes and the protein, SEQ ID NO:7 are absorbed onto a metallic salt particle carrier.

15. The vaccine of claim 1, wherein the adjuvant is a formulation of 0.5 mg AlOH3 and 500 mg of unmethylated immunostimulatory oligonucleotide CpG, wherein the protein SEQ ID NO:7 and unmethylated immunostimulatory oligonucleotide (CpG) are absorbed onto a metallic salt particle carrier.

16. The vaccine of claim 1, wherein the adjuvant is a formulation of 0.25 mg cholesterol, 1 mg dioleoyl phosphotidylcholine, 50µg QS21, and 0.5 mg AlOH3, said formulation consisting of small unilamellar vesicles wherein the QS21 is in the membranes of the vesicles and wherein the vesicles and the protein, SEQ ID NO:7 are absorbed onto a metallic salt particle carrier